

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ART UNIT: 1615	<p align="center"><b><u>CERTIFICATE OF MAILING</u></b>  <b><u>UNDER 37 C.F.R. § 1.8</u></b></p> <p>DATE OF DEPOSIT: <u>June 17, 2011</u></p> <p>I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being submitted on the date indicated above via:</p> <p><input checked="" type="checkbox"/> EFS Web</p> <p><input type="checkbox"/> facsimile to _____</p> <p><input type="checkbox"/> the United States Postal Service with sufficient postage as first class mail addressed to: Mail Stop _____          Commissioner for Patents, P.O. Box 1450,          Alexandria, VA 22313-1450.</p> <p align="right">_____          /Nicole Solomon/          Nicole Solomon</p>
EXAMINER: Danah J. Al- Awadi	
FIRST NAMED INVENTOR: Hans Lennernäs	
SERIAL NO.: 10/576,857	
FILED: 10/7/2008	
CONF. NO.: 8109	
FOR: COMPOSITION COMPRISING BIODEGRADABLE HYDRATING CERAMICS FOR CONTROLLED DRUG DELIVERY	
DOCKET NO.: 02314-26109.PCT.US	

**DECLARATION OF** NIKLAS AXÉN  
**UNDER 37 C.F.R. § 1.132**

THORPE NORTH & WESTERN, LLP  
 8180 South 700 East, Suite 350  
 Sandy, Utah 84070

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

I, Niklas Axén, declare as follows:

1. I am a named inventor in the above-captioned application and the subject matter described and claimed therein.

2. I have a background in Physics and Materials Science. I am an Associate Professor from Uppsala University, and a holder of a PhD in Materials Science. I am Head of Formulation and Process Development at Lids AB.

*N.A*

3. It is my understanding that various claims in the above-recited patent application have been rejected in view of United States Publication No. 2003/0170307 to Royer, filed February 13, 2003, entitled "Inorganic-Polymer Complexes for the Controlled Release of Compounds Including Medicinals" (hereinafter referred to as "Royer").

4. I have reviewed Royer and am familiar with disclosure described therein.

5. Royer is directed towards the use of a complexing agent to control the release profile of the medicinal within its matrix, while the present invention controls the release of the active substance without the need for such a complexing agent.

6. As the Examiner has questioned the criticality of the presently claimed amounts of the expandable agent and sorbed aqueous medium, I have prepared 3 Pastes as outlined in Table 1 and found the following cure times as outlined therein:

Table 1

Components	Paste 1	Paste 2	Paste 3
Calcium Sulphate ( $\text{CaSO}_4 \cdot 1/2\text{H}_2\text{O}$ from Riedel-deHaen) (wt%)	59.41	54.55	46.15
$\text{NaHCO}_3$ (wt%)	0.59	5.45	13.85
Water (deionized) (wt%)	40	40	40
Total (wt%)	100	100	100
Cure Time	3-5 minutes	1 hour	Not cured after 3 hours

7. As shown in Table 1, the varying amounts of sodium bicarbonate greatly affected the cure times of the pastes, differing by at least an order of magnitude between Paste 1 and the other pastes.

N.A.

8. Based on the above, the present claims have been amended to reflect the criticality of the expandable agent, the sorbed aqueous medium, and the resulting cure time.

9. In contrast to the presently claimed amounts, Royer uses sodium bicarbonate in an amount ranging from 5 wt% to 15 wt% as provided in Example 15, page 9 of Royer.

10. The amounts of sodium bicarbonate used in Royer would not provide a cure time of less than 20 minutes for the present compositions.

11. Further, Royer provides no disclosure or recognition that sodium bicarbonate affects cure times of its inorganic-polymer complexes or could be used in the present manner.

12. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statement may jeopardize the validity of the application or any patent issuing thereon.

DATED this 16th day of June, 2011.



Niklas Axén

(name)

N. A.